UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Carmen Rodia

From: Eric Bohnenblust, PhD, Entomologist

Secondary Review: Jennifer Urbanski, PhD, Biologist

Date: January 14, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

This is a short summary of primary reviews of efficacy data. Please find the primary reviews attached.

DP barcode: 424737, 424690, 424736, 424691, 424688
Decision no.: 490524, 490525, 490526, 490527, 490525
Submission no: 959663, 959665, 959667, 959668, 959665
Action code: R310, R310.1, R310.1, R310.1
Product Name: RF2201-08 DFB Block, RF2204-01 DFB Block , RF2203-02 DFB Block, RF2202-04 DFB Block
EPA Reg. No or File Symbol: 89459-O, 89459-A, 89459-T, 89459-I
Formulation Type: Mineral Supplement Feed-Through containing Diflubenzuron
Ingredients statement from the label with PC codes included:

89459-O: Diflubenzuron 0.08%	PC: 108201
89459-A: Diflubenzuron 0.01%	PC: 108201
89459-T: Diflubenzuron 0.02%	PC: 108201
89459-I: Diflubenzuron 0.04%	PC: 108201

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m^2 or mg/cm^2 as appropriate): 0.1 mg/kg/day for cattle, 0.15 mg/kg/day on equine species
Use Patterns: Animal Feed-through

I. Action Requested: Review of data to support label claims against fecal flies on cattle and horses for diflubenzuron

II. Background: Data were submitted to support claims against stable, house, horn, and face flies for a diflubezuron feedthrough for cattle and equine species.

III. MRID Summary: (primary reviews are attached)

49498401. Efficacy of diflubenzuron for the control of horn flies developing in manure from treated animals.

(1) Efficacy of the 0.1 mg/kg/day dose was 98% or higher on days 1-9 when compared to the control treatment. Efficacy of the 30 mg/head/day dose was only 61% on day 1, but efficacy after day one was 99% or 100% when compared to the control treatment.

(2) **Conclusion: Acceptable.** This study is acceptable to support the 0.1 mg/kg/day dose of diflubenzuron in feedstuffs to control horn flies on cattle.

49498402. Efficacy of Diflubenzuron for the control of horn flies developing in manure from treated animals.

(1) Efficacy of the treatments on cattle groups 1 and 2 was 90% or higher for all days tested. For treatment 3, efficacy on cattle was never higher than 72.5%. Doses and compounds specific to each treatment group were not provided.

(2) **Conclusion: Unacceptable.** This study is unacceptable because we do not know what treatments correspond to the labeled products.

49498403. Efficacy of diflubenzuron against pest flies developing in manure from treated animals 1.

(1) Efficacy against the horn fly was 84.17% and 81.47% for the 0.1 and 0.15 mg/kg body weight treatments respectively on day 1. After day 1, efficacy of both treatments against horn flies was between 99-100%. Efficacy of the 0.1 mg/kg dose against the house fly was less than 70% on days 1 and 2. On day three, 93% efficacy was achieved but efficacy during days 4 through 9 was between 75% and 87%. Efficacy of the higher 0.15 mg/kg rate was 69% on day 1, and thereafter was between 83 and 97% except for day 4 when efficacy dipped to 75%. However, the number of flies emerging from the manure on day zero was about 14% of that emerging from the control treatment, and 17% the number of flies emerging from the manure from cows dosed with the lower 0.1 mg/kg treatment, which makes it difficult to know whether the treatment was having an effect, or if the manure from these cows was not optimal for house fly growth and development because emergence from control manure was very low. Efficacy of both the 0.1 and 0.15 mg/kg doses against stable flies was higher than 90% for all days tested.

(2) **Conclusion: Partially Acceptable.** This study supports efficacy claims for the 0.1 and 0.15 mg/kg/day doses of diflubenzuron as a cattle feed-through against horn flies and stable flies. It does not support efficacy claims against house flies.

49498404. TH 6040 as a feed additive for control of the face fly and house fly.

(1) In the lab studies levels as low as 1 ppm caused 100% house fly larval mortality, and the lowest level tested (0.1 ppm) resulted in 71% mortality of house flies. For face flies, rates as low as 0.1 ppm resulted in 100% mortality. In the feeding trials, rates of 0.5 mg/kg resulted in 99% mortality of face fly larvae and 95% of house fly larvae.

(2) **Conclusion: Supplemental.** The study shows diflubenzuron can be effective against face flies in cattle manure, but we cannot confirm the rates used in the lab study correspond to the labeled rate. Also, the lowest effective dose in the feeding study is higher than the label rate.

49498405. Diflubenzuron bolus for control of fly larvae.

(1) In the Kentucky and Kansas field trials, 98%+ mortality of face flies occurred through 14 weeks. After 14 weeks, efficacy was generally around 70% in Kentucky. In the Canadian trial, 100% inhibition of horn fly development occurred through 17 weeks. However, house fly larval mortality never reached 90%. In the Texas trial, 90%+ mortality of horn flies was observed through 5 months after administration of the bolus, and for 3 months after for stable flies.

(2) **Conclusion: Unacceptable.** This study does not support efficacy claims for the labeled products because their directions do not indicate for administration through boluses and rates in mg/a.i./day were not reported.

49498406. Diflubenzuron boluses for fly control on dairy cattle.

(1) In Maryland, the 85:15 ratio of forage to diflubenzuron (rate of 0.078 mg/kg/day) was 90% effective against face flies for 5-6 weeks post bolus, the 50:50 ratio effective for 11-12 weeks, and the 30:70 ratio was effective for 16 weeks. Against house flies, the 85:15 ratio was only effective for 1-2 weeks, the 50:50 and 30:70 ratios were

effective for 3-4 weeks post bolus. In Indiana and Missouri, the bolus treatments were 90% effective against horn flies for 6 weeks post bolus administration, and 90% effective against house flies for 2 weeks after bolus administration. Bolus administration to the cows did not appear to have a consistent effect against populations of adult horn flies or stable flies in Indiana or Missouri.

(2) **Conclusion: Partially Acceptable.** This study was previously reviewed by EPA and was found to support claims against face flies when used on cattle. However, this study does not support claims against house flies, stable flies, or horn flies because of inappropriate design and lack of efficacy at the labeled rate.

IV. RECOMMENDATIONS:

(1) Labeling: All claims relating to horses, ponies, and donkeys should be removed from the label because data were not submitted to show efficacy against equine species.

Data were not adequate to support claims against house flies, or fecal flies on cattle.

Data support claims against stable fly, face fly and horn fly at 0.10 mg/kg/day for cattle.

(a) **The following claims are acceptable on the label for 89459-O (RF2201-08):**
A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy)(cattle) containing diflubenzuron (brand name)] for continuous feeding to (beef)(dairy)(cattle) during the fly season
A (nutritional)(protein)(mineral)(vitamin) supplement containing diflubenzuron (brand name) for continuous feeding of cattle during the fly season
A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy)(cattle) containing diflubenzuron (brand name) for continuous feeding during the fly season
A (nutritional)(protein)(mineral)(vitamin) supplement containing diflubenzuron (brand name)] for continuous feeding to (beef)(dairy)(cattle) during the fly season
A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy) cattle containing diflubenzuron (brand name) for continuous feeding during the fly season
A (nutritional)(protein)(mineral)(vitamin) supplement for (beef)(dairy) cattle containing diflubenzuron (brand name) for continuous feeding to (beef)(dairy) cattle during the fly season
Prevents the emergence of (Stable fly)(Face fly)(and)(Horn fly) from manure of treated cattle
(Stable fly)(Face fly)(and)(Horn fly) larvicide for cattle
(Stable fly)(Face fly)(and)(Horn fly) control for cattle
Controls (Stable fly)(Face fly)(and)(Horn fly) developing in manure of treated cattle
Controls (Stable fly)(Face fly)(and)(Horn fly) growing in manure of treated cattle
Controls (Stable fly)(Face fly)(and)(Horn fly) developing in manure of treated cattle
Stops the development of (Stable fly)(Face fly)(and)(Horn fly) larvae in manure of treated cattle
Prevents the development of (Stable fly)(Face fly)(and)(Horn fly) larvae in manure of treated cattle
Stops the development of (Stable fly)(Face fly)(and)(Horn fly) larvae in manure from treated cattle
Prevents the development of (Stable fly)(Face fly)(and)(Horn fly) larvae in manure from treated cattle
Stops the emergence of adult (Stable flies)(Face flies)(and)(Horn flies) from manure of treated cattle
Prevents the emergence of adult (Stable flies)(Face flies)(and)(Horn flies) from manure of treated cattle
Stops the emergence of adult (Stable flies)(Face flies)(and)(Horn flies) from manure from treated cattle
Prevents the emergence of adult (Stable flies)(Face flies)(and)(Horn flies) from manure from treated cattle
Contains (diflubenzuron)(brand name)
Contains (diflubenzuron)(brand name) a chitin synthesis inhibitor
Breaks the (Stable fly)(Face fly)(and)(Horn fly) life cycle
Can be used as part of an integrated (Stable fly)(Face fly)(and)(Horn fly) control program
Can be used as part of an integrated pest management program
Can be used as part of a total (Stable fly)(Face fly)(and)(Horn fly) control program
Can be used as part of a total pest management program
Can be used as part of a complete (Stable fly)(Face fly)(and)(Horn fly) control program
Can be used as part of a complete pest management program
Solid feed supplement for all classes of (beef) and (dairy) (cattle)

For (beef) and (dairy)(cattle)
Solid feed supplement for (beef) and (dairy)(cattle)
Solid feed supplement for (beef) and (dairy) cattle (only)
For (beef) and (dairy) cattle (only)

The following claims are unacceptable on the label for 89459-O (RF2201-08):
A nutritional)(protein)(mineral)(vitamin) supplement for (horses) (ponies) (donkeys) (and) (mules) (labeled animals) containing diflubenzuron (brand name) for continuous feeding during the fly season
A nutritional)(protein)(mineral)(vitamin) supplement for (horses) (ponies) (donkeys) (and) (mules) (labeled animals) containing diflubenzuron (brand name) for continuous feeding to (horses)(ponies)(donkeys)(and) (mules)(labeled animals) during the fly season
Prevents the emergence of flies from manure of treated (horses)(ponies)(donkeys)(and) (mules)(labeled animals)
Controls flies developing in manure of treated (horses)(ponies)(donkeys) (and)(mules)(labeled animals)
Controls flies growing in manure of treated (horses)(ponies)(donkeys) (and)(mules)(labeled animals)
Stops the development of (House fly)(Stable fly)(Face fly)(and)(Horn fly)(Fecal fly) larvae in manure of treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)
Prevents the development of (House fly)(Stable fly)(Face fly)(and)(Horn fly)(Fecal fly) larvae in manure of treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)
Stops the development of (House fly)(Stable fly)(Face fly)(and)(Horn fly)(Fecal fly) larvae in manure from treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)
Prevents the development of (House fly)(Stable fly)(Face fly)(and)(Horn fly)(Fecal fly) larvae in manure from treated (horses)(ponies)(donkeys)(and)(mules) (labeled animals)
Stops the emergence of adult (House flies)(Stable flies)(Face flies)(and)(Horn flies)(Fecal flies) from manure of treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)
Prevents the emergence of adult (House flies)(Stable flies)(Face flies)(and)(Horn flies)(Fecal flies) from manure of treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)
Stops the emergence of adult (House flies)(Stable flies)(Face flies)(and)(Horn flies)(Fecal flies) from manure from treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)
Prevents the emergence of adult (House flies)(Stable flies)(Face flies)(and)(Horn flies)(Fecal flies) from manure from treated (horses)(ponies)(donkeys)(and)(mules)(labeled animals)
Solid feed supplement for (horses)(ponies)(donkeys)(and)(mules)(labeled animals) (only)
For all classes of (horses)(ponies)(donkeys)(and)(mules)(labeled animals)(only)]
Helps protect your (horse)(pony)(donkey)(and)(mule)(labeled animal) from Flies when you can't be there
Protect Your (Horse)(pony)(donkey)(and)(mule)(labeled animal)] from the pain of Fly Bites
Protect Your (Horse)(pony)(donkey)(and)(mule)(labeled animal)] from the discomfort of Fly Bites
Protect Your (Horse)(pony)(donkey)(and)(mule)(labeled animal)] from Fly Bites
- All of the above claims are unacceptable because efficacy data on horses were not provided

Stops Flies Before They Fly - this is vague and implies a range of things including adult control which data do not support.
Reduce the Risk of Disease & Infection Transmitted by Flies – data do not support this.
Reduce the Risk of Summer Sores – data do not support this.
Clinically proven feed-thru fly control.
Highly Palatable – data do not support highly palatable.
Weather resistant – data showing weather resistance were not submitted.
Approved for lactating and pregnant mares - data need to be submitted for lactating and pregnant mares.
Can be fed to lactating and pregnant mares - data need to be submitted for lactating and pregnant mares.

Prevents the formation of chitin in fly larvae's exoskeletons when they molt
Prevents the formation of chitin in fly larvae's exoskeletons when they molt resulting in their death
Prevents the formation of fly larvae's exoskeletons when they molt resulting in their death
Prevents the formation of fly larvae's exoskeletons when they molt
- the submitted data do not show this

(b). **The following efficacy claims are acceptable on the label for 89459-A (RF2201-01), 89459-T (RF2201-02), 89459-I (RF2201-04) as follows:**

A [(nutritional)(protein)(mineral)(and)(vitamin)] supplement [for (beef)(dairy)(cattle)] containing [(diflubenzuron)(brand name)] for continuous feeding [to (beef)(dairy)(cattle)] during the fly season

Prevents the emergence of horn flies, face flies, and stable flies from manure of treated cattle

(Stable fly)(Face fly)(and)(Horn fly) larvicide for cattle

Controls horn fly, stable fly, and face fly larvae [(developing)(growing)] in manure [of treated cattle

[(Stops)(Prevents the)] development of (Stable fly)(Face fly)(and)(Horn fly) larvae in manure [(of)(from)] treated cattle

[(Stops)(Prevents the)] emergence of adult (Stable flies)(Face flies)(and)(Horn flies) from manure [(of)(from)] treated cattle

Contains [(diflubenzuron)(brand name) (a chitin synthesis inhibitor)]

Breaks the (Stable fly)(Face fly)(and)(Horn fly) life cycle

(Can be used as) part of [(an integrated) a (total) (a complete)] ((Stable fly)(Face fly)(and)(Horn fly) control)(pest management) program

[Solid feed supplement] [for all classes of (beef)and(dairy)]

The following efficacy claims are unacceptable on the label for 89459-A (RF2201-01), 89459-T (RF2201-02), 89459-T (RF2201-04):

Prevents the formation of (chitin in) fly larvae's exoskeletons when they molt (resulting in their death) - data don't show this

Helps Protect Your [(Horse)(pony)(donkey)(and)(mule)(labeled animal)] from Flies When You Can't Be There – data were not submitted for equine species

Stops Flies Before They Fly – this is vague and implies a range of things including adult control which data do not support.

Reduce the Risk of Disease & Infection Transmitted by Flies – data do not support this.

Protect Your [(Horse)(pony)(donkey)(and)(mule)(labeled animal)] from the [pain, discomfort] of Fly Bites - no equine data were submitted.

Reduce the Risk of Summer Sores – data do not support this.

Clinically proven feed-thru fly control – data do not support this.

Highly palatable – data were not submitted to show that it is highly palatable.

Weather resistant - data were not submitted to show weather resistance.

[(Approved for) (Can be fed to)] lactating and pregnant mares – data need to be submitted for lactating and pregnant mares.

EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY)

Primary Reviewer's Name/Title: Eric Bohnenblust, Entomologist

STUDY TYPE:	PRODUCT PERFORMANCE [810.3200]
MRID:	49498401. Efficacy of Diflubenzuron for the control of horn flies developing in manure from treated animals.
DP BARCODE:	424737, 424690, 424736, 424691, 424688
DECISION NO:	490524, 490525, 490526, 490527, 490525
SUBMISSION NO:	959663, 959665, 959667, 959668, 959665
SPONSOR:	Wellmark International
TESTING FACILITY:	New Mexico State University
STUDY DIRECTOR or INVESTIGATOR:	Ron L. Byford
SUBMITTER:	Central Garden and Pet Company
STUDY COMPLETED:	November 2010
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	Not GLP compliant
TEST MATERIAL:	[89459-O, 89459-A, 89459-T, 89459-I] [RF2201-08 DFB Block, RF2204-01 DFB Block , RF2203-02 DFB Block, RF2202-04 DFB Block] [Diflubenzuron 0.08%, Diflubenzuron 0.01%, Diflubenzuron 0.02%, Diflubenzuron 0.04%] [Feed-Through] [Cattle should consume an average of 0.1 mg of diflubenzuron per kg of animal body weight per day]
PROPOSED EFFICACY CLAIMS ON LABEL:	[Prevents the development of/controls house fly, stable fly, face fly, horn fly, and fecal fly larvae in manure]

Efficacy Study Data Evaluation Record

Title: Efficacy of Diflubenzuron for the control of horn flies developing in manure from treated animals.

Purpose/Objective: To evaluate the efficacy of diflubenzuron as a feed-through agent against horn flies.

Materials and Methods

Test Location: New Mexico State University Veterinary Entomology Research Laboratory

Test Material(s): Clarify Larvacide 8% Concentrate (8% diflubenzuron)

Test Dose/Application Rate: 30 mg/head/day, 0.1 mg/kg body weight per day, untreated control

Positive Control/Reference Standard, if used: N/A

Test Species Name, Life Stage, Sex and *Age*: horn flies (*Haematobia irritans*)

Test System:

Describe how each experiment was conducted: Animals were fed diflubenzuron treated feed for 10 days. Each morning beginning on day 1, the freshest pat in each animal's pen was collected for the larval and chemical assays. For the chemical analysis 100 grams of manure was sent to the sponsor for chemical analysis. The remaining manure was frozen for a minimum of 48 hours to kill natural infestations of insect fauna prior to the bioassay. Manure samples were then thawed overnight and placed into three bioassay cups and inoculated with 50 horn fly eggs. The cups were then sealed with paper bags and maintained in a controlled environment until flies could develop or die. Counts of adult flies were recorded and used to determine efficacy.

List the treatments including the untreated control: 30 mg diflubenzuron/head/day (0.066 mg/kg/day for a 1000 lb cow), 0.1 mg diflubenzuron/kg body weight per day, untreated control

Describe test arenas and/or apparatus (include site description and location).

Method(s) of application: Animals were fed one pound of a balanced cattle ration top-dressed with the test substance.

Number of replicates per treatment: 4 animals per treatment, manure was placed into cups which were replicated 3 times per animal (12 cups total) on each day.

Number of individuals per replicate: 50 fly eggs per cup.

Length of exposure to treatment (time in seconds, minutes or hours): Were tested specimens transferred to clean containers? N/A

Experimental conditions (state relative humidity, temperature, and photoperiod): not given.

Data Reported

Results

Efficacy of the 0.1 mg/kg/day dose was 98% or higher on days 1-9 when compared to the control treatment. Efficacy of the 30 mg/head/day dose was only 61% on day 1, but efficacy after day one was 99% or 100% when compared to the control treatment.

Conclusions

This study supports efficacy of the diflubenzuron at 0.1 mg/kg/day against horn flies. Efficacy of the lower dose (30 mg/head/day) against horn flies is not adequate on the first day, but after day one efficacy was high.

Recommendations

This study is acceptable to support the 0.1 mg/kg/day dose of diflubenzuron in feedstuffs against horn flies. In future studies please provide the amount of diflubenzuron that each animal is given so we can confirm that each animal was correctly dosed.

EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY)

Primary Reviewer's Name/Title: Eric Bohnenblust, Entomologist

STUDY TYPE:	PRODUCT PERFORMANCE [810.3200]
MRID:	49498402. Efficacy of an insect growth regulator for the control of house flies developing in manure from treated animals.
DP BARCODE:	424737, 424690, 424736, 424691, 424688
DECISION NO:	490524, 490525, 490526, 490527, 490525
SUBMISSION NO:	959663, 959665, 959667, 959668, 959665
SPONSOR:	Wellmark International
TESTING FACILITY:	New Mexico State University
STUDY DIRECTOR or INVESTIGATOR:	Ron L. Byford
SUBMITTER:	Central Garden and Pet Company
STUDY COMPLETED:	November 22, 2007
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	Not GLP compliant
TEST MATERIAL:	[89459-O, 89459-A, 89459-T, 89459-I] [RF2201-08 DFB Block, RF2204-01 DFB Block , RF2203-02 DFB Block, RF2202-04 DFB Block] [Diflubenzuron 0.08%, Diflubenzuron 0.01%, Diflubenzuron 0.02%, Diflubenzuron 0.04%] [Feed-Through] [Cattle should consume an average of 0.1 mg of diflubenzuron per kg of animal body weight per day]
PROPOSED EFFICACY CLAIMS ON LABEL:	[Prevents the development of/controls house fly, stable fly, face fly, horn fly, and fecal fly larvae in manure]

Efficacy Study Data Evaluation Record

Title: Efficacy of an insect growth regulator for the control of house flies developing in manure from treated animals.

Purpose/Objective: To evaluate the efficacy of diflubenzuron as a feed-through agent against house flies.

Materials and Methods

Test Location: New Mexico State University Veterinary Entomology Research Laboratory

Test Material(s): Diflubenzuron

Test Dose/Application Rate: 0.1 mg/kg body weight per day, untreated control, Doses and compounds specific to each treatment group were not provided.

Positive Control/Reference Standard, if used: N/A

Test Species Name, Life Stage, Sex and *Age*: 1st instar larvae of house flies

Test System:

Describe how each experiment was conducted: Animals were fed diflubenzuron treated feed for 7 days. Each morning beginning on day 3, the freshest pat in each animal's pen was collected for the larval and chemical assays. Manure was then frozen and sent to the sponsor. Manure was sent to the sponsor and three replicates of 25 g from each animal were seeded with 25 first instar house fly larvae. Adult fly emergence was used to measure efficacy.

List the treatments including the untreated control: 0.1 mg diflubenzuron/kg body weight per day?, untreated control

Describe test arenas and/or apparatus (include site description and location).

Method(s) of application: Animals were fed one pound of a balanced cattle ration top-dressed with the test substance.

Number of replicates per treatment: 5 animals per insecticide treatment, 2 animals in the control treatment

Number of individuals per replicate: 25 1st instar house fly larvae per 25 g of manure.

Length of exposure to treatment (time in seconds, minutes or hours): Were tested specimens transferred to clean containers? N/A

Experimental conditions (state relative humidity, temperature, and photoperiod): not given.

Data Reported

Results

Efficacy of the treatments to groups 1 and 2 was 90% or higher for all days tested. For treatment 3, efficacy was never higher than 72.5%.

Conclusions

We cannot draw any effective conclusions because we do not know which treatments correspond to the labeled products, therefore this study does not support any claims against house flies for diflubenzuron feed through products.

Recommendations

This study is unacceptable because we do not know what treatments correspond to the labeled products.

EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY)

Primary Reviewer's Name/Title: Eric Bohnenblust, Entomologist

STUDY TYPE:	PRODUCT PERFORMANCE [810.3200]
MRID:	49498403. Efficacy of diflubenzuron against pest flies developing in manure from treated animals 1.
DP BARCODE:	424737, 424690, 424736, 424691, 424688
DECISION NO:	490524, 490525, 490526, 490527, 490525
SUBMISSION NO:	959663, 959665, 959667, 959668, 959665
SPONSOR:	Wellmark International
TESTING FACILITY:	New Mexico State University
STUDY DIRECTOR or INVESTIGATOR:	Ron L. Byford
SUBMITTER:	Central Garden and Pet Company
STUDY COMPLETED:	November 22, 2007
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	Not GLP compliant
TEST MATERIAL:	[89459-O, 89459-A, 89459-T, 89459-I] [RF2201-08 DFB Block, RF2204-01 DFB Block , RF2203-02 DFB Block, RF2202-04 DFB Block] [Diflubenzuron 0.08%, Diflubenzuron 0.01%, Diflubenzuron 0.02%, Diflubenzuron 0.04%] [Feed-Through] [Cattle should consume an average of 0.1 mg of diflubenzuron per kg of animal body weight per day]
PROPOSED EFFICACY CLAIMS ON LABEL:	[Prevents the development of/controls house fly, stable fly, face fly, horn fly, and fecal fly larvae in manure]

Efficacy Study Data Evaluation Record

Title: Efficacy of diflubenzuron against pest flies developing in manure from treated animals 1.

Purpose/Objective: To evaluate the efficacy of diflubenzuron as a feed-through agent against horn, house, and stable flies.

Materials and Methods

Test Location: New Mexico State University Veterinary Entomology Research Laboratory

Test Material(s): Diflubenzuron 0.04% formulation

Test Dose/Application Rate: 0.1 mg/kg and 0.15 mg/kg body weight per day, untreated control,

Positive Control/Reference Standard, if used: N/A

Test Species Name, Life Stage, Sex and *Age*: 1st instar larvae of house flies, horn flies, stable flies

Test System:

Describe how each experiment was conducted: Animals were fed diflubenzuron treated feed for 10 days. Each morning beginning on day 1, the freshest pat in each animal's pen was collected for the larval and chemical assays. For the chemical analysis 100 grams of manure was sent to the sponsor for chemical analysis. The remaining manure was frozen for a minimum of 48 hours to kill natural infestations of insect fauna prior to the bioassay. Manure samples were then thawed overnight and placed into three bioassay cups per fly species per cow and inoculated with 100 fly eggs. The cups were then sealed with paper bags and maintained in a controlled environment until flies could develop or die. Counts of adult flies were recorded and used to determine efficacy.

List the treatments including the untreated control: 0.1 and 0.15 mg diflubenzuron/kg body weight per day, untreated control

Describe test arenas and/or apparatus (include site description and location).

Method(s) of application: Animals were fed one pound of a balanced cattle ration top-dressed with the test substance.

Number of replicates per treatment: 4 animals per treatment

Number of individuals per replicate: 100

Length of exposure to treatment (time in seconds, minutes or hours): Were tested specimens transferred to clean containers? N/A

Experimental conditions (state relative humidity, temperature, and photoperiod): 80˚F, 12:12 L:D, and 40% humidity.

Data Reported

Results

Efficacy against the horn fly was 84.17% and 81.47% for the 0.1 and 0.15 mg/kg body weight treatments respectively on day 1. After day 1, efficacy of both treatments against horn flies was between 99-100%.

Efficacy of the 0.1 mg/kg dose against the house fly was less than 70% on days 1 and 2. On day three, 93% efficacy was achieved but efficacy during days 4 through 9 was between 75% and 87%. Efficacy of the higher 0.15 mg/kg rate was 69% on day 1, and thereafter was between 83 and 97% except for day 4 when efficacy dipped to 75%. However, the number of flies emerging from the manure on day zero was about 14% of that emerging from the control treatment, and 17% the number of flies emerging from the manure from cows dosed with the lower 0.1 mg/kg treatment, which makes it difficult to know whether the treatment was having an effect, or if the manure from these cows was not optimal for house fly growth and development.

Efficacy of both the 0.1 and 0.15 mg/kg doses against stable flies was higher than 90% for all days tested.

Conclusions

This study shows the diflubenzuron feed through is effective against horn flies and stable flies at both the 0.1 and 0.15 mg/kg/day doses. Neither dose is effective for controlling house fly emergence.

Recommendations

This study supports efficacy claims for the 0.1 and 0.15 mg/kg/day doses of diflubenzuron as a feed-through against horn flies and stable flies. It does not support efficacy claims against house flies.

EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY)

Primary Reviewer's Name/Title: Eric Bohnenblust, Entomologist

STUDY TYPE:	PRODUCT PERFORMANCE [810.3200]
MRID:	49498404. TH 6040 as a feed additive for control of the face fly and house fly. Journal of Economic Entomology. October 1974.
DP BARCODE:	424737, 424690, 424736, 424691, 424688
DECISION NO:	490524, 490525, 490526, 490527, 490525
SUBMISSION NO:	959663, 959665, 959667, 959668, 959665
SPONSOR:	N/A
TESTING FACILITY:	USDA Chemical and Biophysical Control Lab
STUDY DIRECTOR or INVESTIGATOR:	R.W. Miller
SUBMITTER:	Central Garden and Pet Company
STUDY COMPLETED:	Published October 1974
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	Not GLP compliant
TEST MATERIAL:	[89459-O, 89459-A, 89459-T, 89459-I] [RF2201-08 DFB Block, RF2204-01 DFB Block , RF2203-02 DFB Block, RF2202-04 DFB Block] [Diflubenzuron 0.08%, Diflubenzuron 0.01%, Diflubenzuron 0.02%, Diflubenzuron 0.04%] [Feed-Through] [Cattle should consume an average of 0.1 mg of diflubenzuron per kg of animal body weight per day]
PROPOSED EFFICACY CLAIMS ON LABEL:	[Prevents the development of/controls house fly, stable fly, face fly, horn fly, and fecal fly larvae in manure]

Efficacy Study Data Evaluation Record

Title: TH 6040 as a feed additive for control of the face fly and house fly.

Purpose/Objective: To evaluate the efficacy of diflubenzuron as a feed-through agent against face and house flies.

Materials and Methods

Test Location: USDA lab in Beltsville MD

Test Material(s): Diflubenzuron 0.04% formulation

Test Dose/Application Rate: 0.1 mg/kg and 0.15 mg/kg body weight per day, untreated control

Positive Control/Reference Standard, if used: N/A

Test Species Name, Life Stage, Sex and *Age*:

Test System:

Describe how each experiment was conducted:

MATERIALS AND METHODS.—For the laboratory tests, a 25% WP formulation of Thompson-Hayward TH 6040 (*N*-(4-chloro'-phenyl)-*N*-(2,6-difluorobenzoyl)urea) (supplied by Thompson-Hayward Chemical Co., Kansas City, Kans.) was mixed with 1 kg of fresh cow manure at rates from 0.01–10 ppm. Then treated manure containing each amount of compound was divided into 5 paper souffle cups, and each cup was seeded with 25 larvae of the house fly, *Musca domestica* L., or of the face fly, *M. autumnalis* De Geer. Subsequent bioassay procedures were those described previously (Miller et al. 1970).

For the feeding trial, dairy cows were fed TH 6040 (25% WP) at levels of 0, 0.25, 0.5, 1, 5, and 10 mg actual compound/kg body wt (1 cow/level) for a 7-day period. The compound was mixed into the concentrate portion of the ration which also included grass silage and alfalfa hay.

Beginning the day after feeding started and continuing until a day after it stopped, samples of manure were collected daily, taken to the laboratory, and seeded with face fly and house fly larvae as previously described.

Method(s) of application: mixed with manure, or fed to cows

Number of replicates per treatment: 5 for each species

Number of individuals per replicate: 25 larvae for each species

Length of exposure to treatment (time in seconds, minutes or hours): Were tested specimens transferred to clean containers? N/A

Experimental conditions (state relative humidity, temperature, and photoperiod): not given

Data Reported

Results

In the lab studies levels as low as 1 ppm caused 100% house fly larval mortality, and the lowest level tested (0.1 ppm) resulted in 71% mortality of house flies. For face flies, rates as low as 0.1 ppm resulted in 100% mortality. In the feeding trials, rates of 0.5 mg/kg resulted in 99% mortality of face fly larvae and 95% of house fly larvae.

Conclusions

This study shows that rates of 0.5 mg/kg are effective for reducing fly emergence from manure. However, there is no analysis to show the levels of diflubenzuron that would be expected in manure in relation to the artificial rates tested in the laboratory.

Recommendations

This study is supplemental. The laboratory rates are likely to equivalent to levels found in manure, but we cannot confirm this. Further, rates above the label rate were shown to be effective.

EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY)

Primary Reviewer's Name/Title: Eric Bohnenblust, Entomologist

STUDY TYPE:	PRODUCT PERFORMANCE [810.3200]
MRID:	49498405. Diflubenzuron Bolus for Control of Fly Larvae. J.A. Miller, F.W. Knapp, R.W. Miller, C.W. Pitts and J. Weintraub.
DP BARCODE:	424737, 424690, 424736, 424691, 424688
DECISION NO:	490524, 490525, 490526, 490527, 490525
SUBMISSION NO:	959663, 959665, 959667, 959668, 959665
SPONSOR:	N/A
TESTING FACILITY:	Various University Laboratories
STUDY DIRECTOR or INVESTIGATOR:	J.A. Miller
SUBMITTER:	Central Garden and Pet Company
STUDY COMPLETED:	Published 1986
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	Not GLP compliant
TEST MATERIAL:	[89459-O, 89459-A, 89459-T, 89459-I] [RF2201-08 DFB Block, RF2204-01 DFB Block , RF2203-02 DFB Block, RF2202-04 DFB Block] [Diflubenzuron 0.08%, Diflubenzuron 0.01%, Diflubenzuron 0.02%, Diflubenzuron 0.04%] [Feed-Through] [Cattle should consume an average of 0.1 mg of diflubenzuron per kg of animal body weight per day]
PROPOSED EFFICACY CLAIMS ON LABEL:	[Prevents the development of/controls house fly, stable fly, face fly, horn fly, and fecal fly larvae in manure]

Efficacy Study Data Evaluation Record

Title: Diflubenzuron Bolus for Control of Fly Larvae.

Purpose/Objective: To evaluate the efficacy of diflubenzuron boluses as a feed-through agent against face and house flies.

Materials and Methods

Test Location: US and Canada

Test Material(s): 10% Diflubenzuron

Test Dose/Application Rate: 2 - 50 g boluses per steer, untreated control

Positive Control/Reference Standard, if used: N/A

Test Species Name, Life Stage, Sex and *Age*: newly emerged face fly larvae, horn fly larvae, house fly larvae, stable fly larvae depending on location of the test.

Test System:

Describe how each experiment was conducted:

Two groups of tests were conducted; one with molded boluses and another with compressed boluses as they might be produced commercially. Molded boluses were fabricated by pouring the molten wax-based formulation into cylindrical cavities similar to those described by Miller and Miller (1978). The compressed boluses were fabricated by cryogenic grinding of the hardened wax-based formulation into a powder to pass a 30-mesh sieve. The powder was then pressed in a conventional bolus punch and die at ca. 83,000 KPa (12,000 psi) on a commercial bolus press. In both cases the formulation was as described by Miller and Miller (1978).

Molded Boluses

Kentucky and Kansas trials — In each state three cannulated steers were treated with 10% diflubenzuron boluses weighing ca. 50 g placed directly into the steers' respective reticulum. In Kentucky, steers weighing 500, 545 and 591 kg were treated with 2, 2, and 3 boluses, respectively. Two similar but uncannulated steers served as untreated controls. Steers weighing 486, 511, and 502 kg were each treated with two 50 g boluses in the Kansas trial. A single uncannulated steer served as a control.

In both studies, the steers were held in small paddocks and allowed free access to hay, water, and mineral supplement. Each week during the study, the boluses were removed from each cannulated steer, dried with a paper towel, weighed, and returned to the respective steers. Manure samples were taken from all treated and control steers on the same days and bioassayed against face fly larvae. The manure samples were divided into three 100-g subsamples and each seeded with 25 newly emerged larvae. These were incubated at ca. 27°C and held for pupation and adult emergence.

Canadian trial — Two heifers weighing 355 and 370 kg were each given two 50-g 10% diflubenzuron boluses orally with a standard balling gun. Two similar, untreated heifers served as controls. The cattle were held on pasture of mixed alfalfa and tame grass. Manure samples were collected from each treated and each control animal at 1, 3, and 7 d posttreatment and, thereafter, at 2-wk intervals for 20 wk. Manure samples were divided into three subsamples of 1 kg each, placed in enameled pans and seeded with 500 horn fly eggs. Similarly, three subsamples, 1 kg each, were mixed with sawdust and seeded with 2000 housefly eggs. Samples were incubated at ca. 27°C and 65% RH. The production of horn fly pupae and subsequently emerging adults was determined. For housefly bioassays, only the production of adults was determined. In each case, mortality was corrected by Abbott's formula.

Six months after the first treatment, these same two heifers, now weighing 420 and 455 kg, were again given two boluses each and kept in a feedlot on a hay and grain ration. Bioassays of manure were conducted as under pasture conditions.

Texas field trial — Seventeen mature Hereford cows were each treated orally with two 50-g boluses containing 10% diflubenzuron. The cows were then allowed to graze in a > 200-ha pasture of native grasses at Camp Stanley, TX. A herd of 23 cows in an adjacent pasture was the untreated control group.

Ten manure samples were colleted from both treated and untreated cattle at 2-wk intervals. In order to avoid multiple samples from the same animal, we collected only freshly deposited manure at the bedground in the early morning. Manure was taken to the laboratory and frozen to kill arthropods which may have infested the droppings prior to collection. Upon thawing, these samples were each divided into two 100-g subsamples and bioassayed for horn flies and stable flies.

For the horn fly bioassays, 100 eggs were placed on each 100-g sample of manure. The samples were incubated at ca. 27°C. Pupae were extracted from the samples using a flotation procedure. The number of pupae and of subsequently emerging adults was recorded. Stable fly bioassays were conducted in like manner, except that 6 g of fish meal was mixed with each 100-g manure sample prior to seeding with stable fly eggs. It should be noted that in this test, the stable fly was merely used as a model for face fly response since the face fly has not been reported in Texas.

Compressed Boluses

Kerrville study — Twelve Angus steers weighing ca. 270 - 340 kg were divided into three groups of four steers each. The steers in Group A were orally dosed with 10% diflubenzuron boluses at the rate of two 50-g boluses/steer. Group B steers were each treated with two 25-g boluses from the same lot. The remaining group (Group C) served as untreated control. In addition to these steers, three Hereford heifers weighing ca. 300 kg and fitted with rumen cannulas were treated with two 25-g, one 50-g, or two 50-g boluses, respectively. Boluses were placed in the reticulum via the cannula. All cattle were maintained at Kerrville in a common paddock and fed a standard ration of hegari hay and alfalfa cubes with water provided *ad libitum*.

For purposes of manure sampling, the animals were separated individually in small isolation pens for 24 h. Duplicate 50-g samples were collected biweekly from each animal, then frozen, and later bioassayed with horn flies (Miller and Miller 1978). Also at biweekly intervals, boluses in the fistulated animals were removed through the rumen cannulas, observed, weighed, and reinserted into the reticulum.

Beltsville study — Two of three Holstein cows weighing ca. 670 - 700 kg each were treated with 25-g boluses, one with a single bolus and one with four boluses, which were placed directly into the reticulum through a rumen cannula. The third cow served as an untreated control. All three cows were stanchioned and maintained on a corn silage and ground grain ration with water provided *ad libitum*.

Manure samples were collected on three consecutive days prior to treatment, each day for the first 2 wk posttreatment, and twice a week therafter. Duplicate samples of each collection were bioassayed against the face fly according to techniques previously described (Miller and Miller 1978).

Boluses were removed and weighed every 2 wk. In anticipation of residue analysis, both animals were slaughtered and tissue samples collected. The cow treated with four boluses was slaughtered at 2 wk posttreatment, and the one treated with a single bolus was killed at 8 wk posttreatment.

Method(s) of application: bolus

Number of replicates per treatment: 3 cows per state in Kentucky and Kansas, Two cows in Canada, and 17 cows in Texas trials.

Number of individuals per replicate: 25 – 100 dependent on fly species

Length of exposure to treatment (time in seconds, minutes or hours): Were tested specimens transferred to clean containers? N/A

Experimental conditions (state relative humidity, temperature, and photoperiod): typical field conditions for livestock

Data Reported

Results

In the Kentucky and Kansas field trials, 98%+ mortality of face flies occurred through 14 weeks. After 14 weeks, efficacy was generally around 70% in Kentucky. In the Canadian trial, 100% inhibition of horn fly development occurred through 17 weeks. However, house fly larval mortality never reached 90%. In the Texas trial, 90%+ mortality of horn flies was observed through 5 months after administration of the bolus, and for 3 months after for stable flies.

Efficacy was inconsistent for all groups with compressed boluses.

Conclusions

This study does not support efficacy claims for the labeled products because their directions do not indicate for administration through boluses, and we cannot calculate an effective rate in mg/kg/day.

Recommendations

This study is unacceptable to support efficacy claims.

EFFICACY STUDY DATA EVALUATION RECORD (COMPLETED STUDY)

Primary Reviewer's Name/Title: Eric Bohnenblust, Entomologist

STUDY TYPE:	PRODUCT PERFORMANCE [810.3200]
MRID:	49498406. Diflubenzuron Boluses for Fly Control on Dairy Cattle. R.W. Miller, R.D. Hall, R.E. Williams, L.G. Pickens, and K.A. Doisy.
DP BARCODE:	424737, 424690, 424736, 424691, 424688
DECISION NO:	490524, 490525, 490526, 490527, 490525
SUBMISSION NO:	959663, 959665, 959667, 959668, 959665
SPONSOR:	N/A
TESTING FACILITY:	Various Laboratories
STUDY DIRECTOR or INVESTIGATOR:	J.A. Miller
SUBMITTER:	Central Garden and Pet Company
STUDY COMPLETED:	Published April 1991
CONFIDENTIALITY CLAIMS:	none
GOOD LABORATORY PRACTICE:	Not GLP compliant
TEST MATERIAL:	[89459-O, 89459-A, 89459-T, 89459-I] [RF2201-08 DFB Block, RF2204-01 DFB Block , RF2203-02 DFB Block, RF2202-04 DFB Block] [Diflubenzuron 0.08%, Diflubenzuron 0.01%, Diflubenzuron 0.02%, Diflubenzuron 0.04%] [Feed-Through] [Cattle should consume an average of 0.1 mg of diflubenzuron per kg of animal body weight per day]
PROPOSED EFFICACY CLAIMS ON LABEL:	[Prevents the development of/controls house fly, stable fly, face fly, horn fly, and fecal fly larvae in manure]

Efficacy Study Data Evaluation Record

Title: Diflubenzuron Bolus for Control of Fly Larvae.

Purpose/Objective: To evaluate the efficacy of diflubenzuron boluses as a feed-through agent against face and house flies.

Materials and Methods

Test Location: Maryland, Missouri, and Indiana

Test Material(s): 9.7% Diflubenzuron

Test Dose/Application Rate: bolus sizes were not specified

Positive Control/Reference Standard, if used: N/A

Test Species Name, Life Stage, Sex and *Age*: newly emerged face fly larvae, horn fly larvae, house fly larvae, stable fly larvae depending on location of the test.

Test System:

Describe how each experiment was conducted:

Four separate trials were conducted. Two of these were conducted in Maryland, one in Indiana, and one in Missouri. In Maryland one study was conducted to determine the effect of diflubenzuron boluses on milk production. A total of 56 high-producing Holstein cows were randomly divided into two groups of 28 cows each. Each cow in the treated group received two 9.7% commercial diflubenzuron boluses (Vigilante®, American Cyanamid Co., Wayne, New Jersey). The boluses were administered to stanchioned animals with a standard balling gun. To simulate the stress of bolusing, the balling gun was also placed into the mouths of the untreated control cattle. Cattle were fed a total mixed ration consisting of corn silage, alfalfa haylage, alfalfa hay, and a concentrate mixture ad libitum (see Table 1 for composition of concentrate) and were allowed access to pasture when not in the barn. Milk from individual cows was weighed at each milking. The percentages of milk fat and milk protein were determined by the Dairy Herd Improvement Association (DHIA) supervisor on milk samples taken during wks 6 and 11 postbolusing. Data from this trial were analyzed by covariance analyses (SAS Institute 1985) using milk production data for 3 wk prior to the start of the trial and milk component data from DHIA sampling performed 3 wk prior to the start of the trial as the covariates.

In the second experiment in Maryland, a total of 30 Holstein cows were used. These cows were divided into three groups and were fed total mixed rations containing three forage-to-concentrate ratios (85:15, 50:50, 30:70). The forage component of the rations consisted of 60% corn silage and 40% alfalfa silage on a dry matter basis (see Table 1 for composition of concentrate). Two cows in each group served as untreated controls, four cows in each group were administred one bolus containing 9.7% of a flaked formulation of diflubenzuron (EF), and four cows received one bolus containing 9.7% of a powdered formulation of diflubenzuron (EP).

Two of the four cows in each bolus group had rumen fistulas, and every 2 wk after administration of the boluses, the boluses were removed from the cows via the fistula, weighed, and placed back into the reticulum. At the same time, a sample of rumen fluid was removed and a pH determination was made. Once a week after administration of the boluses, ca. 1 kg of fresh feces was taken from each cow and frozen until bioassayed with face flies and house flies as previously described (Scott et al. 1986).

In addition to the studies in Maryland, field trials with the two types of boluses were conducted in Indiana and Missouri. In Indiana, three commerical dairy farms with each ca. 150 head of cattle were used. One herd served as an untreated control farm; on the other two farms all cattle over ca. 136 kg body weight were bolused. Cattle on one farm received EF boluses and cattle on the other farm received EP boluses. Cattle weighing between 136-249 kg received one-half of a bolus and cattle weighing more than 250 kg received one bolus.

Horn, face, stable, and house fly counts were made biweekly starting 2 wk postbolusing and continuing through 20 wk postbolusing. Horn and face fly counts were made by counting these species on each of 25 randomly selected adult cows in each herd. Stable fly counts were made by counting the number of stable flies landing during a 10- to 15-s interval on the front legs of 25 randomly selected cows. House fly numbers were estimated with a Scudder Grid placed in five locations on each farm. All house flies landing on the grid in 30 s were counted.

Five fresh ca. 500-ml fecal samples were collected at wks 2, 6, 10, 15, and 20 from each of the treated herds, and one sample was collected from the control herd. These samples were frozen for later bioassay with house and horn flies.

In Missouri during the third week of May, 195 Holstein and Guernsey cows were treated with the EP boluses and placed on ca. 30 ha of pasture. At the same time, 85 dairy heifers were treated with the EF boluses and pastured on 19 ha located a half mile to the east. Boluses were administered at the same rate as in Indiana. Fifty dry dairy cows pastured on 12 ha between the two test herds served as an untreated control herd. These herds were fed silage throughout the trial. Due to the lack of an adjoining feedlot facility at the control site, house and stable fly counts were taken at a similar facility housing untreated Charolais cattle approximately 16 km away.

Starting 2 wk postbolusing and continuing through 20 wk postbolusing, horn flies were counted on one side, and face flies were counted on the faces of 25 head of cattle. These counts were made on Holstein-bred animals that were not lactating. House flies on the farms were determined by the number of flies landing on Scudder Grids during a 30-s interval. Three counts were taken on each farm on each sampling date. Stable fly numbers were estimated by counting the number of stable flies captured on 24 William's traps (Williams 1973) at each sampling date. Manure samples were collected and treated as in Indiana.

Method(s) of application: bolus

Number of replicates per treatment: 2 at most for on cow studies

Number of individuals per replicate: 28 cows and 10 cows in the two Maryland experiments, 150 cows in Indiana, 195 cows in Missouri.

Length of exposure to treatment (time in seconds, minutes or hours): Were tested specimens transferred to clean containers? N/A

Experimental conditions (state relative humidity, temperature, and photoperiod): typical field conditions for livestock

Data Reported

Results

In Maryland, the 85:15 ratio of forage to diflubenzuron was 90% effective against face flies for 5-6 weeks post bolus, the 50:50 ratio effective for 11-12 weeks , and the 30:70 ratio was effective for 16 weeks. Against house flies, the 85:15 ratio was only effective for 1-2 weeks, the 50:50 and 30:70 ratios were effective for 3-4 weeks post bolus.

In Indiana and Missouri, the bolus treatments were 90% effective against horn flies for 6 weeks post bolus administration, and 90% effective against house flies for 2 weeks after bolus administration.

Bolus administration to the cows did not appear to have a consistent effect against populations of adult horn flies or face flies in Indiana or Missouri.

Previous EPA reviews indicate that the lowest efficacious rate of diflubenzuron in this study against face flies was 0.078 mg/kg/day. The lowest efficacious rate for other species was 0.15 mg/kg/day for those species where the products were effective.

Conclusions

This study supports claims against face flies at the 0.1 mg/kg/day rate on cattle; however, it does not support efficacy claims against horn flies, house flies, or stable flies for the labeled products because their directions do not indicate for administration through boluses, and efficacious rates

were above the labeled rate for cattle, and on animal adult fly counts are not adequate to evaluate efficacy of feed-through products.

Recommendations

This study is partially acceptable.